MAR 1 3 2013

SECTION 5 – 510(k) Summary
Modified Capiox® SX Oxygenator and Hardshell Reservoir

TERUMO

Submitter Information:

Contact:

This submission was prepared in February 2013 by:

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This submission was prepared for:

Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
Registration #1124841

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
Capiox® SX18 Hollow Fiber Oxygenator with detachable Hardshell Reservoir	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Blood Gas Oxygenator
	Cardiopulmonary Bypass Blood Reservoir (Code: DTN)	Blood Reservoir
Capiox® SX25 Hollow Fiber Oxygenator with detachable Hardshell Reservoir	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Blood Gas Oxygenator
	Cardiopulmonary Bypass Blood Reservoir (Code: DTN)	Blood Reservoir
X-Coated Capiox® SX18 Hollow Fiber Oxygenator with/without detachable Hardshell Reservoir	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Blood Gas Oxygenator
	Cardiopulmonary Bypass Blood Reservoir (Code: DTN)	Blood Reservoir
X-Coated Capiox® SX25 Hollow Fiber Oxygenator with/without detachable Hardshell Reservoir	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Blood Gas Oxygenator
	Cardiopulmonary Bypass Blood Reservoir (Code: DTN)	Blood Reservoir
Capiox® Hardshell Reservoir	Cardiopulmonary Bypass Blood Reservoir (Code: DTN)	Blood Reservoir

Predicate Devices:
The device submitted in this 510(k) maintains characteristics that are substantially equivalent in intended use, design, technology/principles of operation, materials and specifications to the following devices:

CAPIOX® SX18 Hollow Fiber Oxygenator with Detachable Hardshell Reservoir
(K961000)

CAPIOX® SX25 Hollow Fiber Oxygenator with Detachable Hardshell Reservoir
(K962667)

X-Coated CAPIOX® SX18 and SX25 Hollow Fiber Oxygenators with/without Detachable Hardshell Reservoirs
(K993772)

Capiox® RX Hardshell Reservoir
(K013526)

Intended Use:
The intended use remains the same as the intended use in the cleared submissions (K961000, K962667, K993772, and K013526). There have been no changes to the indications or intended use of the modified devices as a result of the addition of the positive pressure relief valve.

Intended Use for Oxygenator/Reservoir Product:
The (X-Coated) Capiox® SX25 and SX18 Hollow Fiber Oxygenators with/without Detachable Hardshell Reservoirs are used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery for periods up to 6 hours.

The integral heat exchanger is used to warm or cool blood or perfusion fluid as it flows through the device.

The (detachable) hardshell reservoir is used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal.

The Hardshell Reservoir is also used for post-operative chest drainage and autotransfusion procedures to aseptically return the blood to the patient for blood volume replacement.

The Hardshell Reservoir is also used with the vacuum-assisted venous return technique during cardiopulmonary bypass.

(The X-Coating™ is a polymer coating that is applied to blood contacting surfaces of the oxygenator to reduce the adhesion of platelets to the surfaces of the device.)

Intended Use for Reservoir Only Product:
The Capiox® Hardshell Reservoir is a hardshell reservoir used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal.

The Hardshell Reservoir is also used for post-operative chest drainage and autotransfusion procedures to aseptically return blood to the patient for blood volume replacement.

The Hardshell Reservoir is also used with the vacuum-assisted venous return technique during cardiopulmonary bypass.

The Hardshell Reservoir contains X-Coating, which is intended to reduce platelet adhesion on the surfaces of the device.

The device may be used for procedures lasting up to 6 hours.

Principles of Operation and Technology:
The technological characteristics and principles of operation remain the same as that of the predicate devices previously cleared (K961000, K962667, K993772, and K013526) for all devices in this submission. There have been no changes to the fundamental scientific technology of the modified devices.

The modified and predicate Capiox SX Oxygenator utilizes porous fiber technology to facilitate the transfer of gases between a blood-phase environment and a gas-phase environment for the intent of satisfying the gas exchange needs of a patient during cardiopulmonary bypass surgery. A fiber bundle offers the porous membrane surface to sufficiently permit the movement of gases through the walls of the hollow fibers via diffusion.

The modified and predicate Capiox SX Oxygenator has an integrated heat exchanger that is comprised of stainless steel encased in a polycarbonate housing. The stainless steel acts as a heat transfer material that permits heat that is generated from a temperature controlled external water bath to transverse across the walls of the stainless steel to effect the necessary temperature change upon circulating blood.

With respect to the filtration of blood, the modified and predicate Capiox Hardshell Reservoir relies upon mechanical entrapment of particulates and emboli within the filter mesh as a means to remove those particulates from the blood.

Design and Materials:
With respect to the design of the oxygenator, the design of the modified Capiox SX oxygenator device is unaffected by the changes being incorporated at this time. The subject of this Special 510(k) is a modification being made to the Hardshell Reservoir.

With respect to the design of the Hardshell Reservoir, the reservoir component remains identical to the design of the original reservoir that was cleared by FDA with (K961000, K962667, K993772, and K013526) – except that a positive pressure relief valve will be included in the lid of the reservoir. The intent of the relief valve is to eliminate excessive pressure that *could* accumulate in a reservoir during bypass procedures.

The materials that are used in the construction of the CAPIOX® SX Oxygenator/Hardshell Reservoir may include, but are not limited to, nylon, polycarbonate, stainless steel, polyvinyl chloride, polyurethane, polyester, polypropylene, polyethylene, and X-Coating™.

Terumo Cardiovascular Systems concludes that the differences between the modified device and the predicate device do not affect the intended use of the device nor do they affect safety and effectiveness of the device when used as labeled.

Performance Evaluations:
Clinical studies involving patients are not necessary to demonstrate substantial equivalence of the subject device to the predicate devices. Substantial equivalence is demonstrated with the following *in-vitro* performance evaluations:

- Assessment of Reservoir Pressure during Simulated Bypass Procedures
- Positive and Negative Pressure Testing of the Reservoir
- Pressure Relief Valve performance following application of vacuum to the reservoir
- Pressure Relief Valve-to-Reservoir Interface Testing
- Usability Testing
- Sterilization Assessment
- Shock Drop and Vibration Testing
- Artificial Conditioning to Shelf-Life of the product

Substantial Equivalence Comparison:
In demonstrating substantial equivalence of the *modified* CAPIOX® SX Oxygenator/Hardshell Reservoir to the predicate CAPIOX® SX Oxygenator/Hardshell Reservoir, a comparative study and/or assessment was performed in each of the following areas:

- Intended use
- Target Population
- Duration of use
- Product labeling
- Product design
- Materials
- Principles of Operation and Technology
- Device Performance

Substantial Equivalence Statement:
The modified CAPIOX® SX Oxygenator/Hardshell Reservoir and the predicate CAPIOX® SX Oxygenator/Hardshell Reservoir are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the subject device and the predicate devices do not raise new issues of safety and effectiveness.

Conclusion:
Based upon the comparative studies and analyses, Terumo Cardiovascular Systems concludes that the *modified* CAPIOX® SX Oxygenator/Hardshell Reservoir is *substantially equivalent* to the predicate *modified* CAPIOX® SX Oxygenator/Hardshell Reservoir. It is further concluded that any recognized differences noted during the assessments do not raise new issues of patient/user safety or product effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2013

Terumo Cardiovascular Systems Corporation
c/o Suzanne Grenier
125 Blue Ball Road
Elkton, MD 21921

Re: K130359
Trade/Device Name: CAPIOX SX18 and SX25 Hollow Fiber Oxygenators (with/without X-Coating), with/without Detachable Hardshell Reservoirs; and CAPIOX RX Hardshell Reservoir
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: February 12, 2013
Received: February 13, 2013

Dear Ms. Grenier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – Indications for Use
Modified Capiox® SX Oxygenator and Hardshell Reservoir

510(k) Number (if known): Unknown at time of Submission

Device Name:

Capiox® SX18 Hollow Fiber Oxygenator with detachable Hardshell Reservoir

Capiox® SX25 Hollow Fiber Oxygenator with detachable Hardshell Reservoir

X-Coated Capiox® SX18 Hollow Fiber Oxygenator with/without detachable Hardshell Reservoir

X-Coated Capiox® SX25 Hollow Fiber Oxygenator with/without detachable Hardshell Reservoir

Indications For Use:

The (X-Coated) Capiox® SX25 and SX18 Hollow Fiber Oxygenators with/without Detachable Hardshell Reservoirs are used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery for periods up to 6 hours.

The integral heat exchanger is used to warm or cool blood or perfusion fluid as it flows through the device.

The (detachable) hardshell reservoir is used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal.

The Hardshell Reservoir is also used for post-operative chest drainage and autotransfusion procedures to aseptically return the blood to the patient for blood volume replacement.

The Hardshell Reservoir is also used with the vacuum-assisted venous return technique during cardiopulmonary bypass.

(The X-Coating™ is a polymer coating that is applied to blood contacting surfaces of the oxygenator to reduce the adhesion of platelets to the surfaces of the device.)

Prescription Use ~~XX~~ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner

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K130359

SECTION 4 – Indications for Use
Modified Capiox® SX Oxygenator and Hardshell Reservoir

510(k) Number (if known): Unknown at time of Submission

Device Name:

Capiox® Hardshell Reservoir

Indications For Use:

The Capiox® Hardshell Reservoir is a hardshell reservoir used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal.

The Hardshell Reservoir is also used for post-operative chest drainage and autotransfusion procedures to aseptically return blood to the patient for blood volume replacement.

The Hardshell Reservoir is also used with the vacuum-assisted venous return technique during cardiopulmonary bypass.

The Hardshell Reservoir contains X-Coating, which is intended to reduce platelet adhesion on the surfaces of the device.

The device may be used for procedures lasting up to 6 hours.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner